UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION	CASE NO. 05-340 (KAJ) (consolidated)
THIS DOCUMENT RELATES TO: *Walgreen* (05-404)	

AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Walgreen Co., Eckerd Corporation, The Kroger Co., Maxi Drug, Inc. d/b/a Brooks Pharmacy, Albertson's, Inc., Safeway, Inc. and Hy-Vee, Inc. (collectively "Plaintiffs") sue Defendants Abbott Laboratories, Fournier Industrie et Santé, and Laboratories Fournier S.A., and for their Amended Complaint allege as follows:

Nature of the Action

1. This is a civil antitrust action seeking treble damages and other relief arising out of Defendants' unlawful monopolization of the market for fenofibrate, a drug used to lower cholesterol and triglycerides, which is manufactured and sold by Defendants under the brand name TriCor. As described in more detail below, Defendants have unlawfully delayed and impeded generic competition to TriCor by numerous means, including undertaking *two* expensive and unnecessary product conversions that were designed solely to switch users from one form of the drug to a different form of the drug in order to impede generic competition. Defendants' conduct had the purpose and effect of maintaining Defendants' monopoly in the fenofibrate market.

Defendants' unlawful conduct has deprived Plaintiffs and other purchasers of the benefits of generic competition from the first half of 2002 through the present.

Parties

2. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business in Deerfield, Illinois. Walgreen owns and operates retail stores in several states at which it dispenses prescription drugs to the public. During the relevant period, Walgreen purchased TriCor directly from Defendants. Walgreen brings this action in its own behalf and (with respect to certain purchases) as the assignee of a pharmaceutical wholesaler, AmerisourceBergen Corporation, which purchased TriCor directly from Defendants during the relevant period for resale to Walgreen.

3. Plaintiff Eckerd Corporation ("Eckerd") is a Delaware corporation having its principal place of business in Warwick, Rhode Island. Eckerd owns and operates retail stores in several states at which it dispenses prescription drugs to the public. During the relevant period, Eckerd purchased TriCor directly from Defendants. Eckerd brings this action in its own behalf and (with respect to certain purchases) as the assignee of a pharmaceutical wholesaler, McKesson Corporation ("McKesson), which purchased TriCor directly from Defendants during the relevant period for resale to Eckerd.

4. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its principal place of business in Cincinnati, Ohio. Kroger owns and operates retail stores in several states at which it dispenses prescription drugs to the public. During the relevant period, Kroger purchased TriCor directly from Defendants.

5. Plaintiff Maxi Drug, Inc. d/b/a Brooks Pharmacy ("Brooks") is a Delaware corporation having its principal place of business in Warwick, Rhode Island. Brooks owns and operates retail stores in several states at which it dispenses prescription drugs to the public. During the relevant period, Brooks purchased TriCor either directly from Defendants or from McKesson, which purchased it directly from Defendants for resale to Brooks. Brooks brings this action in its own behalf and as McKesson's assignee.

6. Plaintiff Albertson's, Inc. ("Albertson's") is a Delaware corporation having its principal place of business in Boise, Idaho. Albertson's owns and operates retail stores in several states at which it dispenses prescription drugs to the public. During the relevant period, Albertson's purchased TriCor from McKesson, which purchased it directly from Defendants for resale to Albertson's. Albertson's brings this action in its own behalf and as McKesson's assignee.

7. Plaintiff Safeway, Inc. ("Safeway") is a Delaware corporation having its principal place of business in Pleasanton, California. Safeway owns and operates retail stores in several states at which it dispenses prescription drugs to the public. During the relevant period, Safeway purchased TriCor from McKesson, which purchased it directly from Defendants for resale to Safeway. Safeway brings this action in its own behalf and as McKesson's assignee.

8. Plaintiff Hy-Vee, Inc. ("Hy-Vee") is an Iowa corporation having its principal place of business in West Des Moines, Iowa. Hy-Vee owns and operates retail stores in several states at which it dispenses prescription drugs to the public. During the relevant period, Hy-Vee purchased TriCor from McKesson, which purchased it directly from Defendants for resale to Hy-Vee. Hy-Vee brings this action in its own behalf and as McKesson's assignee.

9. Defendant Abbott Laboratories ("Abbott") is an Illinois corporation having its principal place of business in Abbott Park, Illinois. Abbott develops, manufactures and sells brand-name pharmaceutical products and other products in the United States and elsewhere.

10. Defendants Fournier Industrie et Santé and Laboratories Fournier, S.A. (collectively "Fournier") are French corporations having their principal place of business at 42 Rue de Longvie, 21300 Chenove, France.

11. Defendants Abbott and Fournier acted in concert in devising and carrying out the anticompetitive scheme described below. Each Defendant authorized and knowingly participated in each of the unlawful acts alleged below, and each Defendant received the benefits of those unlawful acts.

Jurisdiction and Venue

12. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26. The Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337(a).

13. Venue is proper in this Court pursuant to section 12 of the Clayton Act, 15 U.S.C. § 22, because each Defendant is an inhabitant of this District or is found or transacts business there.

Trade and Commerce

14. The pharmaceutical products at issue in this case are sold in interstate commerce, and the unlawful activities alleged in this Complaint have occurred in, and have had a substantial effect upon, interstate commerce.

Characteristics of Pharmaceutical Markets

15. The sale of pharmaceutical products in the United States contains a significant market imperfection that can be exploited by manufacturers in order to create or maintain monopoly power with respect to the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to buy. When the person who chooses the product also pays for it, the price of the product plays an appropriate role in the buyer's choice of product and the manufacturer of the product has an appropriate incentive to lower its price.

16. The pharmaceutical industry is characterized by a "disconnect" between the payment obligation and product selection. State laws prohibit pharmacists from dispensing a large class of pharmaceutical products, including fenofibrate, without a prescription from the patient's physician. This prohibition on dispensing drugs without a prescription creates a disconnect between the payment obligation and product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the product, but the patient's physician chooses which product the patient will buy.

17. Many pharmaceutical manufacturers, including Abbott, exploit this defect in pharmaceutical markets. The so-called brand manufacturers (i.e., the manufacturers of branded, as opposed to generic, pharmaceuticals) employ large forces of sales representatives, known as "detailers," who visit physicians' offices in an effort to persuade physicians to prescribe the manufacturer's products. These detailers do not advise physicians regarding the cost of their company's products. Studies show that physicians typically are not aware of the relative cost of branded pharmaceutical products and that, even when physicians are aware of relative cost, they are

insensitive to price differences because they do not themselves have the obligation to pay for the products. The result is a marketplace in which price plays a relatively unimportant role in product selection.

18. The relative unimportance of price in pharmaceutical markets reduces what economists call the price elasticity of demand—the extent to which sales go down when price goes up—which in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing sales. The ability to raise price above marginal cost without losing sales is referred to by economists and antitrust courts as market power or monopoly power. Thus, the net result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain monopoly power.

19. Congress sought to ameliorate the disconnect, and to restore some of the normal competitive pressures to the pharmaceutical marketplace, by authorizing the manufacture and sale of generic pharmaceuticals. State legislatures continued the same policy by mandating or permitting generic substitution by pharmacists without physician approval. When a pharmacist receives a prescription for a branded pharmaceutical product, and a generic version of that product is available, state law permits (or in some cases requires) the pharmacist to dispense the generic product instead of the branded product. In this way, the importance of price is reintroduced to the product selection decision at the pharmacy counter, and the marketplace disconnect is ameliorated. Branded pharmaceutical manufacturers lose their ability to exploit the market imperfection, their monopoly power dissipates, and some normal competitive pressures are restored.

20. For example, if Defendants' unlawful conduct had not prevented generic manufacturers from successfully entering the market with a generic version of Abbott's TriCor

product in 2002, direct purchasers of TriCor would have saved more than $1 billion in the purchase of fenofibrate from that time to the present.

21. In order to continue to exploit this market disconnect and maintain their monopoly power, and thereby avoid losing more than $1 billion in monopoly profits, it was necessary for Defendants to prevent the successful introduction of generic TriCor. Beginning in the second half of the 1990's, Defendants foresaw the commencement of generic competition and began devising ways to delay or impede that competition. In response to this anticipated competitive threat, Defendants devised a so-called "life cycle management" scheme which involved (among other things) expensive and unnecessary product modifications that would deliver no benefits to patients but would effectively shield TriCor from generic competition. The scheme was extraordinarily successful—so successful that it was nominated for Abbott's Life Cycle Management Award, given to the pharmaceutical product team that is most effective in thwarting generic competition. Defendants' anticompetitive scheme is described in detail below.

Federal Regulation of New Pharmaceutical Products

22. Under the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, approval by the Food and Drug Administration ("FDA") is required before a new drug may be sold in interstate commerce. Premarket approval for a new drug must be sought by filing a new drug application with the FDA, under either section 355(b) or section 355(j) of the Act, demonstrating that the drug is safe and effective for its intended use.

23. In 1984, Congress amended the Food, Drug and Cosmetic Act by enacting the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Amendments or the Hatch-Waxman Act. Hatch-Waxman simplified the regulatory hurdles

for prospective generic drug manufacturers by eliminating the need for generic companies to file lengthy and costly New Drug Applications ("NDAs") in order to obtain FDA approval. Instead, such companies are permitted to file Abbreviated New Drug Applications ("ANDAs") and to rely on the safety and effectiveness data already supplied to the FDA by the brand-name manufacturer. Hatch-Waxman also added a number of patent-related provisions to the statutory scheme, as described below. Congress's principal purpose in enacting the Hatch-Waxman Amendments was "to bring generic drugs onto the market as rapidly as possible." *Mova Pharmaceuticals Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998).

24. New drugs that are approved for sale by the FDA are sometimes protected by a patent or patents, which provide the patent owner with the exclusive right to sell that drug in the United States for the duration of the patent or patents involved, plus any extensions. Under 21 U.S.C. § 355(b)(1), a patent holder seeking FDA approval for a new drug is required to "file with the FDA the patent number and expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Patent information received by the FDA with respect to approved drugs is published in a book entitled "Approved Drug Products With Therapeutic Equivalence Evaluations," commonly known as the "Orange Book," where it can be found and consulted by future FDA applicants.

25. Generic drugs are drugs which the FDA has found to be bioequivalent to brand name drugs. The first generic competitor to enter a market typically does so at a price at least 30% lower than the price of the equivalent brand-name drug and quickly takes a substantial amount

of market share away from the brand-name manufacturer. As additional generic competitors come to market, the price of the generics continues to fall, and their combined market share continues to grow. In some cases, generic competitors sell products equivalent to brand-name prescription drugs for as little as 10% of the price of the brand-name drug, and have captured as much as 90% of the brand-name drug's pre-generic sales.

26. The price competition engendered by generic drug manufacturers benefits all purchasers of the drug, at all levels of the distribution chain, who are able to buy the same chemical substance at much lower prices. Retail pharmacies, such as those owned and operated by Plaintiffs, substitute generic drugs for brand-name drugs wherever possible in order to lower their own costs and those of their customers.

Abbreviated New Drug Applications for Generic Drugs

27. Under Hatch-Waxman, a drug manufacturer may seek expedited FDA approval to market a generic version of a brand-name drug by filing an ANDA pursuant to 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand-name drug.

28. An applicant filing an ANDA for a generic version of a brand-name drug must certify to the FDA that one of the following conditions is satisfied: (1) the brand-name manufacturer has not filed patent information with the FDA (a "paragraph I certification"); (2) the patent or patents have expired (a "paragraph II certification"); (3) the patent will expire on a particular future date, and the generic manufacturer does not seek to market its generic product before that date (a "paragraph III certification"); or (4) the patent is invalid and/or will not be infringed by the generic manufacturer's product (a "paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii). If an

unexpired patent has been listed in the Orange Book by the brand-name manufacturer, a generic applicant is required to file either a paragraph III or a paragraph IV certification.

29. If a generic manufacturer submits a paragraph IV certification stating that a listed patent is invalid or will not be infringed, it must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

30. The patent owner, upon receiving a paragraph IV certification from an ANDA applicant, has 45 days in which to initiate a premarketing patent infringement action against the applicant (a cause of action created by Hatch-Waxman). If no action is initiated within 45 days, FDA approval of the generic proceeds without regard to patent issues. However, if a patent infringement lawsuit is brought within the 45-day window, the FDA is automatically barred from granting final approval to the generic applicant until 30 months after the patent holder's receipt of the Paragraph IV certification, unless the patent expires or is held invalid or noninfringed first. 21 U.S.C. § 355(j)(5)(B)(iii). This automatic stay of FDA approval is triggered without regard to the merits of the patent holder's lawsuit.

31. The Hatch-Waxman Amendments and the federal regulations that implement them do not give the FDA authority to resolve issues of patent law. The FDA is required to accept as true information it obtains from patent holders, and to withhold its approval of new generic drugs whenever the patent holder presents a litigated dispute (whether genuine or not) regarding the validity or infringement of a patent.

32. One result of the statutory and regulatory provisions described above is that brand-name manufacturers have a strong incentive to obtain, list and enforce patents against prospective generic applicants even if the patent is ultimately held to be invalid or not infringed by

the generic applicant's proposed generic drug. If a brand-name manufacturer is able to obtain a patent from the Patent and Trademark Office, list the patent in the Orange Book and bring actions under the Hatch-Waxman Act to enforce the patent, the brand-name manufacturer can effectively block the entry of generic competition for up to 30 months. This delay, which is triggered without regard to the merit of the patent holder's claim, can be worth hundreds of millions of dollars to the manufacturer of a successful brand-name drug.

33. A second result of these provisions is that generic applicants are dependent on the existence of an identical FDA-approved brand-name drug in order to take advantage of the simplified ANDA approval process created by Hatch-Waxman and successfully market a generic drug. FDA regulations, which are concerned only with safety and efficacy and not with effects on competition, permit branded manufacturers to seek FDA approval to modify the dosage form, strength and other characteristics of their existing products. Importantly, the regulations do not require the brand manufacturer to make public the fact that the manufacturer is seeking FDA approval for these modifications. Thus, it is possible for an unscrupulous branded manufacturer to make slight alterations to its product and obtain FDA approval for the slightly altered product in anticipation of the commencement of generic competition to its original product.

34. If the brand manufacturer withdraws the original product (drug 1) from the market and replaces it with the slightly different drug (drug 2), the generic applicant can continue to pursue an ANDA for a generic version of drug 1 only by seeking and obtaining a determination from the FDA that drug 1 was not withdrawn for safety or effectiveness reasons. 21 C.F.R. § 314.122. If the brand manufacturer not only withdraws drug 1 from the market but also uses its detail force and other methods to ensure that physicians stop writing prescriptions for drug 1, even

surmounting this additional hurdle and obtaining FDA approval will be of little practical benefit to the generic applicant or to the public, because no prescriptions will be written for drug 1 and the approved generic product will not be substitutable for drug 2. Under these circumstances, the generic applicant's only real alternative is to start over and submit a new ANDA seeking approval to market a generic version of drug 2, which will add several years to the approval process and therefore put off the commencement of generic competition for several years.

TriCor (Fenofibrate)

35. TriCor is used to reduce high-levels of low-density lipoprotein cholesterol ("LDL-C"), sometimes referred to as "bad cholesterol," and triglycerides by promoting the dissolution and elimination of fat particles in the blood. TriCor also increases levels of high-density lipoprotein cholesterol ("HDL-C"), sometimes referred to as "good cholesterol," and reduces LDL-C in patients with primary hypercholesterolemia (high bad cholesterol) or mixed dyslipidemia (high bad cholesterol and high triglycerides). TriCor is also effective at reducing triglycerides in patients with hypertriglyceridemia (high triglycerides). The active ingredient in TriCor is fenofibrate.

36. Fenofibrate is a fibrate. Fibrates, statins, bile acid sequestrants, and niacin are categories of cholesterol-lowering drugs. Each of those categories addresses cholesterol conditions differently, each has different side effects (some more serious than others), and each has different efficacy profiles in (i) reducing LDL-C, (ii) raising HDL-C, and (iii) lowering triglycerides. A cholesterol-lowering drug from any of the four categories is not reasonably interchangeable with a drug from another of the categories, and in most cases two drugs within any of the four categories are not reasonably interchangeable with one another.

37. The use of the drug substance fenofibrate as a cholesterol-lowering agent is not new. It has been known since at least the early 1980's, and Fournier's fenofibrate-based drug product Lipidil was approved for use in the United States by at least 1993. Defendants' conduct, described below, allowed Defendants to maintain a monopoly on fenofibrate despite the fact that fenofibrate is not protected by any valid patent.

38. On January 23, 1990, the U.S. Patent and Trademark Office ("PTO") granted Fournier's patent application as U.S. Patent No. 4,895,726 (the "'726 patent"). The '726 patent is titled "Novel Dosage Form of Fenofibrate." In its '726 patent, Fournier claims a dosage form of fenofibrate containing a co-micronized mixture of particles of fenofibrate and a solid surfactant. A solid surfactant is a surface-active agent that interacts with the surfaces of poorly soluable substances, such as fenofibrate, to help them dissolve. A micronized substance is one that has been reduced in size to the micron size range.

39. The specification, claim language and prosecution history of the '726 patent explain what is meant by a co-micronized mixture of fenofibrate and a solid surfactant, and each of these sources makes it clear that such a mixture is obtained when (and only when) fenofibrate and solid surfactant are first mixed together and then micronized as an "intimate" mixture that excludes other components. The patent term "co-micronization of fenofibrate and a solid surfactant" is defined in the patent as "the micronization of an intimate mixture of fenofibrate and a solid surfactant." The patent specifically asserts that this co-micronization process improves the bioavailability of the fenofibrate to a greater extent than would be achieved merely by adding a surfactant, by micronizing the fenofibrate on its own, or by intimately mixing the separately micronized fenofibrate and surfactant. Fournier limited the patent claims to a co-micronized mixture

of fenofibrate and a solid surfactant in order to overcome a rejection of the claims as obvious based on the prior art.

40. In December 1999, Fournier filed for reexamination of the '726 patent. The reexamination proceedings for the '726 patent also dictate a construction of the patent claims as requiring that the co-micronization step be performed on a mixture consisting solely of fenofibrate and a solid surfactant and not including additional excipients.

41. In 1997, Fournier granted Abbott an exclusive license to the '726 patent in the United States. Defendants submitted separate NDAs for three strengths of branded fenofibrate capsules they intended to market. The FDA approved the TriCor 67mg capsule NDA on February 9, 1998, and the TriCor 134 mg and 200 mg capsule NDAs on June 30, 1999. Defendants jointly brought each of these products to market shortly after receiving FDA approval, and sales of the capsule rose quickly to top $158 million by 2000, and $277 million in 2001.

Defendants' Exclusionary Scheme to Thwart Generic Competition

A. *The Illinois Patent Litigation*

42. On December 14, 1999, Novopharm Limited (subsequently acquired by Teva Pharmaceuticals USA, Inc. ("Teva")) filed an ANDA with the FDA requesting approval to market generic fenofibrate 67 mg capsules (the "Teva capsule ANDA") before the expiration of the '726 patent. The Teva capsule ANDA was later amended by Novopharm to request approval to market generic fenofibrate 134 mg and 200 mg capsules. Novopharm submitted a paragraph IV certification describing its proposed capsule product and stating that the proposed product did not infringe the '726 patent.

43. On May 9, 2000, Impax Laboratories, Inc. ("Impax") also filed an ANDA for fenofibrate capsules. Impax similarly sought approval to market its fenofibrate capsules prior to the expiration of the '726 patent, and accordingly certified under Paragraph IV that its product did not infringe the '726 patent, and duly and timely notified Abbott of its ANDA.

44. On or about April 7, 2000, August 18, 2000 and March 19, 2001, respectively, Defendants initiated a series of infringement actions in the United States District Court for the Northern District of Illinois, against Teva (and its subsidiary, Novopharm) and Impax, alleging infringement of the '726 patent under 35 U.S.C. § 271(e)(2)(A) (collectively, the "Illinois Patent Litigation"). Under Hatch Waxman, these suits imposed 30-month stays on FDA approval of Teva's and Impax's generic products. As explained in more detail below, each of these actions was both objectively and subjectively a sham.

45. The FDA granted Impax tentative approval for Impax's fenofibrate capsules on February 20, 2002. However, the automatic 30-month stay prevented FDA from granting final approval to Impax's capsule ANDA.

46. On March 19, 2002, the Illinois district court granted Teva's motion for summary judgment of non-infringement of the '726 patent in the Illinois Patent Litigation. In so doing, the Court construed various elements of the '726 patent based on the lexicography and prosecution history of the patent and concluded that Teva's generic fenofibrate capsule product did not literally infringe the terms of the patent. The court also held that Defendants were estopped from asserting a range of equivalents which might be construed to include Teva's generic fenofibrate product. The district court's decision was affirmed by the Federal Circuit on March 20, 2003.

47. Teva subsequently received final FDA approval to market its 134 mg and 200 mg capsules, and tentative approval to market its 67 mg capsules, on April 9, 2002, and began selling the 134 mg and 200 mg products shortly thereafter. Teva received final approval for its 67 mg capsule on September 3, 2002.

48. On March 26, 2003, the Illinois district court granted Impax's motion for summary judgment of non-infringement of the '726 patent based, *inter alia*, on Impax's assertion of collateral estoppel on the basis of the earlier summary judgment that had been granted in the Teva infringement actions. The FDA subsequently granted Impax final FDA approval to market its fenofibrate capsule products on October 28, 2003.

B. *The First Exclusionary Product Conversion*

49. Defendants knew that merely by filing the Illinois Patent Litigation within 45 days of receiving notice of the ANDA filings from Teva and Impax, they would prevent the FDA from granting final approval to Teva and Impax for up to 30 months, despite the fact that Defendants' patent lawsuits lacked any merit at all. Thus, even though Defendants had no basis to file the Illinois Patent Litigation, and knew it, they also knew that doing so would delay competition from Teva's and Impax's generic fenofibrate capsule products for up to 30 months.

50. Using the time they obtained by filing meritless patent litigation, Defendants modified the dosage form and strength of their TriCor product so that the Teva and Impax generic products would not be substitutable. Defendants then engaged in additional actions aimed at thwarting generic competition.

51. As of September 3, 2001, Defendants sold TriCor in capsule form and in strengths of 67 mg, 134 mg and 200 mg ("TriCor A"). On September 4, 2001, Defendants obtained

FDA approval to market a TriCor tablet formulation in 54 mg and160 mg strengths ("TriCor B"). Defendants obtained this approval while the Illinois Patent Litigation was still ongoing, and while the 30-month stays of Teva's and Impax's generic fenofibrate capsules were still in effect. TriCor B offered no benefits of any kind to consumers because it contained the same drug as TriCor A and was bioequivalent to the capsules. However, in this case TriCor B offered huge benefits to Defendants because, unlike TriCor A, there were no pending ANDAs seeking approval to market generic versions of TriCor B at this time.

52. As of September 2001, Abbott knew that the automatic stay in the Illinois Patent Litigation would not be lifted for many months. In or about September 2001, Defendants announced that they would stop all sales of TriCor A, and directed their sales force to market only TriCor B and to pressure doctors not to write prescriptions for TriCor A. In this way, Defendants intended to convert the market from TriCor A to TriCor B—that is, to ensure that there were no prescriptions written for TriCor A and no TriCor A in the market with which to fill any such prescriptions—well before generic versions of TriCor A could be launched.

53. As of September 2001, Defendants knew that a typical retail pharmacy maintains only a 30-60 day supply of most pharmaceutical products. By refusing to sell TriCor A, Defendants ensured that by early 2002—long before the expected entry of generic versions of TriCor A—retail pharmacies would no longer have branded TriCor A in inventory.

54. Defendants' draining of TriCor A from the distribution channel prior to generic entry had an anticompetitive purpose and effect. As a result of this draining, there was little or no TriCor A available in the marketplace between January 2002 and April 2002 (when Teva entered). As explained above, Defendants took steps to ensure that physicians stopped writing

prescriptions for TriCor A and started writing prescriptions for TriCor B instead. To the extent that a physician nevertheless wrote a prescription for TriCor A, Defendants' draining of the distribution channel ensured that there would be no TriCor A available at the pharmacy to fill such a prescription. As a matter of good pharmacy practice and continuity of patient care, a pharmacist who received such a prescription during this time would call the prescribing physician and ask for permission to switch the prescription to the closest available product, TriCor B. Defendants thus used retail pharmacies as unwitting detailers to convert any stray physicians who continued to write prescriptions for the discontinued product.

55. Defendants' channel-draining strategy was especially effective at defeating generic substitution because TriCor is a maintenance medication, i.e., a medication taken over a long period of time to treat a chronic condition. Prescriptions for TriCor are typically written for a 30-day supply with a number of refills (as many as 12) permitted. Had Defendants not drained the channel of TriCor A, pharmacists could have continued to fill existing TriCor A prescriptions with TriCor A up to the point at which Teva's generic version of TriCor A became available. At that point pharmacists could have satisfied the remaining refills with generic TriCor A. Defendants' channel-draining tactic ensured that pharmacists would run out of TriCor A before generic TriCor A became available, thereby ensuring that the patient's prescription would have to be switched to TriCor B and preventing Teva from gaining a foothold for the generic in the market.

56. Teva eventually overcame the automatic stay resulting from Defendants' sham patent cases and entered the market in April 2002. As discussed above, by that time Defendants' exclusionary tactics had ensured that few if any new prescriptions for TriCor A were

being written and that, because of the channel-draining strategy, any refillable TriCor A prescriptions had already been switched to TriCor B.

57. However, there still existed some possibility that a physician would continue to prescribe TriCor A, for which Teva's generic version of TriCor A could be dispensed, or that a pharmacist receiving a prescription for TriCor B would call the physician to ask for permission to dispense generic TriCor A instead. It is the policy of most retail pharmacies, including Plaintiffs, to dispense generic pharmaceutical products whenever possible. Defendants were aware of these policies and took additional steps to thwart even this possibility of generic competition.

58. More than 75% of all prescriptions are dispensed to patients covered by some form of third-party plan (an insurer, HMO, Medicaid, etc.). For large retail chains, the percentage of third-party prescriptions is even higher—at or above 90%. Most third-party plans subscribe to a data service provided by First Data Bank, a pharmaceutical information vendor, which indicates whether a particular drug is a branded drug or a generic drug. Third-party plans use this information to carry out the terms of their benefit plans, which typically include higher patient co-payments for branded drugs and lower co-payments for generic drugs.

59. In or about December 2001, Defendants caused First Data Bank to list as "obsolete" the TriCor A product code in its National Drug Data File ("NDDF"). Under the policy followed by First Data Bank (a policy of which Defendants were aware), this "obsolete" listing resulted in First Data Bank identifying Teva's product as a *branded* drug rather than a generic drug. Defendants thereby required third-party customers to pay the higher co-payments associated with branded pharmaceuticals in order to receive Teva's fenofibrate product.

60. The practice of many retail pharmacies is that they will not call a physician to ask for permission to switch a prescription, even if the pharmacy would benefit financially, unless the patient would also save money. Moreover, very few if any patients would agree to a switch unless they would save money. Defendants' "obsoleting" of TriCor A in the NDDF effectively eliminated any financial benefit to the patient from filling a prescription with Teva's generic version of TriCor A, further hampering generic competition.

61. Defendants' tactic of causing TriCor A to be listed as obsolete in the NDDF had an anticompetitive effect even before the Teva product was launched. Under the policy of some third-party plans, such a listing of TriCor A caused the plans to no longer cover TriCor A under the plan at all (i.e., prescriptions for TriCor A would no longer be reimbursed by the plan). In those instances, many pharmacists presented with a TriCor A prescription would call the physician to ask for permission to switch the prescription to a product that was covered by the plan, namely TriCor B. Defendants' exclusionary conduct in causing TriCor A to be listed as obsolete thus had the effect of causing TriCor A prescriptions to be switched to TriCor B before Teva's generic version of TriCor A was launched.

62. TriCor B offered no therapeutic benefits to consumers relative to TriCor A because it contained the same active ingredient as TriCor A and was therapeutically equivalent and bioequivalent to TriCor A. Indeed, Defendants obtained FDA approval for TriCor B by relying on the same clinical studies on which they had relied in seeking approval for TriCor A and by demonstrating to the FDA that TriCor B was bioequivalent to TriCor A. In fact, the introduction of TriCor B was actually disadvantageous to patients taking TriCor A because of the well-documented likelihood of patient confusion inherent in changing patients from one medication to

another having a different dosage strength. Thus, Defendants' introduction of TriCor B was expensive, unnecessary and potentially confusing to patients. Defendants launched TriCor B solely in order to thwart and delay generic competition.

63. Defendants sought to obtain approval for a new indication for TriCor B, which was for "raising HDL-C levels in adult patients with Frederickson Types IIa and IIb dyslipidemia." In doing so, however, Defendants relied upon the same clinical studies that had been submitted in support of their NDA for TriCor A. *See* Medical Officer's Review of New Drug Application, August 30, 2000 (available at http://www.fda.gov/cder/foi/nda/2001/21-203_Tricor_medr.pdf).

64. Although these same studies were available to obtain this same indication for TriCor A, Defendants intentionally did not seek approval for this indication for TriCor A and instead sought it only for TriCor B. Defendants chose not to seek such an indication for TriCor A in order to inhibit generic competition. Defendants were then able to exploit this illusory differentiation between TriCor B and TriCor A in their marketing efforts on behalf of TriCor B.

65. In addition to the medical facts, the economic facts also establish that TriCor B was not a superior product to TriCor A. If TriCor B were in fact superior to TriCor A, Defendants would have developed and marketed TriCor B sooner than they did. Defendants' delay in developing and marketing TriCor B until just before the onset of generic competition is evidence that Defendants developed and marketed TriCor B not because of any therapeutic benefits, but solely because of its effectiveness in protecting TriCor from generic competition.

66. Likewise, if TriCor B were a superior product to TriCor A, Defendants would have reflected that superiority in the pricing of TriCor B. Rather than pricing TriCor B at a premium to TriCor A, Defendants introduced TriCor B at a price equal to that of TriCor A.

67. Defendants invested significant resources in developing, obtaining FDA approval for, and marketing TriCor B. Defendants incurred these substantial expenses in order to sell a product that was therapeutically equivalent and bioequivalent to, and was priced the same as, a product that was already on the market. Defendants' conduct made no economic sense except for its effectiveness in thwarting generic competition.

68. The purpose and effect of Defendants' strategy was to thwart generic competition that otherwise would have existed in sales of fenofibrate capsules. By engaging in this scheme, Defendants did not simply choose not to sell TriCor A; they took additional steps that had the purpose and effect of destroying any market for TriCor A (and its generic equivalent) before Teva or Impax could enter the market.

69. As a result of Defendants' exclusionary conduct, Teva and Impax were denied the opportunity to effectively launch their generic fenofibrate products, and were excluded from the most efficient means of distributing their products. When Teva was finally able to launch its fenofibrate capsule, Teva captured only 5% of the fenofibrate market. This is in stark contrast to the "generic erosion" normally observed upon the launch of a generic bioequivalent to a branded product, where generics typically capture from 40% to 80% (or more) of the brand's sales within the first year of launch. As for Impax, Defendants' exclusionary tactics were so effective that Impax abandoned altogether its plans to enter the market with generic TriCor A. Thus, as a direct and proximate result of Defendants' overall scheme to monopolize, Defendants effectively destroyed

generic competition that should have started in the first half of 2002, and have improperly maintained a 95% share of the market for fenofibrate products.

C. ***The Delaware Patent Litigation***

70. Having successfully shielded their product (and monopoly profits) from generic competition, Defendants were quick to return to the same strategy when generic competitors once again threatened to enter the fenofibrate market. This time before this Court, Defendants executed their scheme of reflexively filing patent suits against generic competitors, notwithstanding the lack of merit in such suits, while using the resulting delay to convert the fenofibrate market to a product not susceptible to generic substitution.

71. Recognizing that Defendants' product conversion had successfully defeated the launch of generic TriCor A, Teva started over and began seeking FDA approval for a generic version of TriCor B. On or around June 17, 2002, Teva filed with the FDA an ANDA for its generic fenofibrate 54 mg and 160 mg tablets (the "Teva Tablet ANDA"), along with a Paragraph IV certification that the ANDA did not infringe the '726 patent or two additional patents that Defendants had subsequently listed in the Orange Book as covering the TriCor tablets, U.S. Patent No. 6,074,670 (the "'670 patent"), which issued on June 13, 2000, and U.S. Patent No. 6,277,405 (the "'405 Patent"), which issued on August 21, 2001. On or around August 21, 2002, Teva gave notice to Defendants of the filing of the Teva Tablet ANDA and the Paragraph IV certifications made therein. Abbott received notice of Teva's initial ANDA filing on August 26, 2002.

72. Teva subsequently amended its ANDA, on July 29, 2003 and December 17, 2003, respectively, by filing two additional Paragraph IV certifications, one for U.S. Patent 6,589,552 (the "'552 patent") and one for U.S. Patent 6,652,881 (the "'881 patent"), shortly after

Abbott listed each of these patents in the Orange Book as claiming TriCor. Teva duly served Abbott with notice of each of its certifications, which prompted additional infringement complaints filed within 45 days of each notice.

73. In three separate complaints filed in the United States District Court for the District of Delaware (later consolidated into a single action), Abbott alleged that Teva had infringed the five patents as to which Teva had filed Paragraph IV certifications. The first complaint, filed on October 4, 2002, alleged infringement of the '726 Patent, the '670 patent, and the '405 patent; the second complaint was filed on August 29, 2003, alleging infringement of the '552 patent; and the third complaint was filed January 22, 2004, alleging infringement of the '881 patent.

74. By virtue of the filing of the first and second complaints, Defendants imposed two successive 30-months stays under Hatch-Waxman, thus barring FDA approval of Teva's ANDA. The first 30-month stay was triggered by the first complaint (involving the '726, '670 and '405 patents) and expired on February 26, 2005, 30 months after Abbott received Teva's first notice letter. The second 30-month stay was generated by the second complaint filed involving the '552 patent, and was set to expire in February 2006. Because (and only because) of the modifications to Hatch-Waxman made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Defendants were not entitled to a third stay based on the third complaint for infringement of the '881 patent.

75. Similarly, Impax also sought to enter the fenofibrate market in the United States by filing an ANDA for fenofibrate tablets in or around December 2002. In connection with this ANDA, Impax submitted Paragraph IV certifications that the ANDA did not infringe the '726, the '670 and the '405 patents. As they had against Teva, Defendants sued Impax, asserting

infringement of the '670 and the '405 patents. The filing of the initial infringement case, on January 23, 2003, triggered an automatic 30-month stay of approval of Impax's Tablet ANDA by the FDA. The issuance and Orange Book listing of the '552 patent resulted in an additional infringement case against Impax, and an additional 30 month stay. The listing of the '881 patent resulted in yet another suit against Impax, but again, as in the case of the suits against Teva, there was no additional 30-month stay associated with that infringement suit.

76. On March 5, 2004, the FDA granted tentative approval to Impax's and Teva's tablet ANDAs, which meant that the FDA had determined that these generic products are bioequivalent to TriCor tablets of the same dosage strength, and that Teva and Impax have satisfied all the other regulatory requirements, such as demonstrating safety and efficacy, for the sale of their fenofibrate product in the United States. The tentative approvals by the FDA would have been final approvals but for the successive 30-month stays resulting automatically from Abbott's and Fournier's filing and maintenance of their patent infringement actions against Impax and Teva concerning the tablet ANDAs. Both Teva and Impax have represented to this Court that, absent the 30-month stays, they would have received final approval on March 5, 2004, and would have entered the market shortly thereafter with 54 mg and 160 mg generic tablets.

77. If it had not been for the first exclusionary product modification from TriCor A to TriCor B, Teva and Impax likely would not have submitted ANDAs for tablets and, even if they had, Defendants likely would not have filed the meritless patent cases that kept Teva's and Impax's generic tablets off the market after March 5, 2004 because generic erosion would already have occurred. Thus, but for the first conversion, either the product would have been marketed

exclusively in capsule form or, even if tablets had been introduced, generic versions of the tablet would have become available in early 2004.

78. The various infringement suits in Delaware against Teva and Impax were consolidated before this Court (the "Delaware Patent Litigation"). The Delaware Patent Litigation was heavily litigated by and among Defendants, Teva and Impax, and trial was scheduled to begin on December 6, 2004. Defendants succeeded in getting this trial date pushed back six months to June 6, 2005, however, through the filing of the subsequent infringement actions related to the '552 patent. Then, with less than a month to go before trial, having already achieved the only goal of these lawsuits (delay), Defendants voluntarily moved to dismiss all the pending Delaware infringement actions. Defendants' voluntary dismissal demonstrated that their intention all along was not to pursue the merits of their infringement claims, but merely to delay generic competition.

D. ***Defendants' Sham Patent Litigation***

79. All of the Illinois Patent Litigation, and substantial portions of the Delaware Patent Litigation, were both objectively and subjectively a sham.

Non-infringement

80. In the Illinois Patent Litigation, Abbott and Fournier alleged that Teva's and Impax's proposed generic versions of TriCor A infringed Fournier's '726 patent. This allegation of patent infringement was objectively baseless, and Defendants knew that it was objectively baseless. The Illinois Patent Litigation was brought not because Defendants believed they had a realistic chance of prevailing in the litigation, but rather because by filing the litigation, regardless of its outcome, Defendants were able to delay generic competition for up to 30 months.

81. As explained earlier, the claims, specification, original prosecution history and reexamination prosecution history of the '726 patent made it absolutely clear that the patent is limited to a fenofibrate formulation in which co-micronization is performed on a mixture of fenofibrate and a solid surfactant without the presence of additional excipients. As Defendants were aware from Novopharm's paragraph IV certification, Teva's proposed generic capsule was not made using co-micronization.

82. Under Teva's process, fenofibrate was first pre-micronized on its own and in the absence of any other ingredient. The pre-micronized fenofibrate was then dry mixed with lactose monohydrate, pregelatinized starch, croscarmellose sodium and crossprovidone. After some additional steps, including wet granulation and drying, the dried, granulated mixture was then dry blended with additional excipients to produce granules that can pass through a #16 mesh screen. The granulated mixture was then blended again, weighed and stored for eventual encapsulation into gelatin capsules. Impax's proposed generic capsule was made using a similar process.

83. Since it was obvious that the '726 patent claims were limited to a formulation in which fenofibrate and a solid surfactant are co-micronized in the absence of other excipients, and equally obvious that Teva's and Impax's proposed products were not made using such a process, no reasonable litigant could have realistically expected to prove infringement against either generic applicant under 35 U.S.C. § 271(e)(2)(A). In fact, neither Abbott nor Fournier expected to do so. Abbott and Fournier knew that it was only a matter of time before their claim was defeated, but time was exactly what they were seeking. Abbott and Fournier needed to delay approval of Teva's and Impax's ANDAs long enough for them to convert the market to TriCor B, and the Illinois Patent Litigation gave them sufficient time to do so.

84. As noted above, the Illinois district court granted summary judgment to Teva in the Illinois Patent Litigation in March 2002, finding that the '726 patent claims had to be construed in the manner described in the patent and that, so construed, Teva's proposed generic capsule did not infringe any of those claims. The district court had no difficulty in reaching this conclusion. The trial court's ruling was affirmed only a year later by the United States Court of Appeals for the Federal Circuit, which likewise had no difficulty in rejecting Defendants' position. As the Federal Circuit pointed out in its opinion, the specification of the patent and other circumstances made it "abundantly clear that 'co-micronization of . . . fenofibrate and a solid surfactant' should be construed as referring to co-micronization of a mixture consisting essentially of fenofibrate and solid surfactant." *Abbott Laboratories v. Novopharm Ltd.*, 323 F.3d 1324, 1330 (Fed. Cir. 2003).

85. Even after their defeat in the action against Teva, Defendants continued to press the same infringement allegations against Impax. When Impax argued that Defendants were collaterally estopped by the claim construction ruling issued by the district court in the prior litigation against Teva, Defendants made the frivolous arguments that collateral estoppel did not apply because (1) "a district court is not bound by another court's claim construction"; (2) the district judge in the prior action "misunderstood the pharmaceutical technology and issues in the '726 patent"; and (3) the ruling was on appeal. *See Abbott Laboratories v. Impax Laboratories, Inc.*, 2003 WL 1563426, *4-5 & n.4 (N.D. Ill. 2003). Each of these arguments was contrary to controlling Supreme Court or Federal Circuit precedent, and each was easily rejected by the Illinois district court.

86. In the Delaware Patent Litigation, Defendants alleged that Teva's and Impax's proposed generic versions of TriCor B infringed the '726, '670, '405, '552 and '881 patents. Defendants had no factual basis for such allegations at the time they were made. Defendants had performed no tests of any kind on the Teva product before alleging infringement, despite the fact that Teva had provided samples of its product to Defendants. Moreover, as Teva explained to Defendants in its paragraph IV certifications, Teva's product did not in fact infringe any of the patents asserted by Defendants. There was no infringement of Defendants' patents, there was no basis to allege infringement, and Defendants made no effort to determine whether or not there was infringement before filing suit.

87. In connection with each of the paragraph IV certifications made by Teva and Impax, Teva and Impax were required to and did provide Defendants with detailed statements explaining why their proposed generic products did not infringe any of Defendants' patents. Teva also provided Defendants with technical material from its ANDA demonstrating the lack of infringement.

88. In fact, Defendants did not file the Delaware Patent Litigation because they believed they had a chance of prevailing in the litigation or because they genuinely hoped to prevail. Defendants filed the Delaware Patent Litigation solely because, merely by filing those cases, they were able once again to trigger a regulatory delay of up to 30 months in FDA approval of Teva's and Impax's ANDAs.

89. Defendants continued to prosecute the Delaware Patent Litigation even though they had no factual basis to allege infringement of any of Defendants' patents. Defendants

did not conduct any tests on any unexpired Teva fenofibrate tablets until May of 2005, almost three years after they had filed the first of the Delaware patent cases.

90. With respect to the '726 patent, Defendants' allegations of infringement in the Delaware Patent Litigation were objectively baseless and unreasonable for the same reason that those allegations were baseless and unreasonable in the Illinois Patent Litigation. Indeed, at the time they alleged infringement of the '726 patent in the Delaware litigation, Defendants' proffered claim construction had already been rejected by the Illinois district court in its March 2002 ruling granting Teva summary judgment, and Defendants were collaterally estopped by that ruling. Teva's and Impax's proposed fenofibrate tablet products did not infringe the '726 patent for the same reason that their proposed fenofibrate capsule products did not infringe the '726 patent, and Defendants were so informed in Teva's and Impax's paragraph IV certifications.

91. Defendants' allegations that Teva's proposed product infringed the '670 patent, claim 9 of the '405 patent and the '552 patent rested on Defendants' interpretation of the patent term "hydrophilic polymer." That interpretation was objectively baseless and unreasonable in the context of the Delaware Patent Litigation. Defendants' interpretation was directly contrary to the definition of "hydrophilic polymer" contained in the patents themselves and was rejected by this Court in its *Markman* rulings for that reason. Under the construction of "hydrophilic polymer" contained in the patents themselves and adopted by this Court, each of these patent claims required a product containing at least 20% by weight hydrophilic polymer, while it was undisputed that Teva's proposed tablet product contained only 7.7% by weight hydrophilic polymer. Under these circumstances, no reasonable litigant could have realistically expected a court to find infringement. In fact, Defendants did not allege infringement of the '670 patent, claim 9 of the '405 patent and the

'552 patent because they believed they had a chance of establishing infringement, but solely to trigger the 30-month stay and thereby delay the commencement of generic competition.

Inequitable Conduct

92. Defendants were guilty of inequitable conduct in obtaining the '881 patent, and knew they were guilty of inequitable conduct. Inequitable conduct renders a patent unenforceable in any action against an alleged infringer. In listing and attempting to enforce a patent that they knew to be unenforceable, Defendants engaged in conduct that was both objectively and subjectively a sham.

93. The '881 patent resulted from U.S. Patent Application No. 10/288,425, filed November 6, 2002. The '881 patent is owned by Fournier. Fenofibrate has limited solubility and, according to the '881 patent, the poor solubility of fenofibrate interferes with its bioavailability, causing bioavailability to be "incomplete." The '881 patent asserts that there is a need to improve fenofibrate bioavailability by achieving a dissolution that is "close to 100% over very short periods of time."

94. The '726 patent, also owned by Fournier, describes a fenofibrate formulation that is prior art to the '881 patent. As explained above, the '726 patent also discloses a method of improving fenofibrate solubility, and thus bioavailability, by co-micronizing fenofibrate with a surfactant. Lipanthyl 200M, a fenofibrate pharmaceutical product sold by Fournier in Europe, is an embodiment of the '726 patent and is the same formulation as TriCor A.

95. The '881 patent defines the requirements for dissolution as greater than 10% in five minutes, 20% in ten minutes, 50% in 20 minutes and 75% in 30 minutes in a medium comprised of 1200 ml water to which 2% Polysorbate 80 is added, or of 1000 ml of water to which

0.025 M sodium lauryl sulfate is added, with a blade rotation speed of 75 rpm. The patent asserts that these higher dissolution requirements are met "by a new method for preparing a pharmaceutical composite by spraying a suspension of the active ingredient onto an inert hydrosoluble carrier."

96. During the prosecution of the application that led to the '881 patent, the Examiner rejected prosecution claims 1-14 and 22-41 as obvious over the '726 patent. In response to this rejection, Fournier distinguished the '726 patent by its dissolution profile, arguing that the invention being claimed "has an unexpectedly superior dissolution profile" compared to the prior art disclosed in the '726 patent.

97. The Examiner allowed the claims, finding that the '726 patent failed to teach a composition having a dissolution of at least 10% in five minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes. According to the Examiner's Statement of Reasons for Allowance, the "instant invention [claimed in the '881 patent] has an unexpectedly superior dissolution profile compared to Lipanthyl® 200M (as taught by [the '726 patent])." Thus, the dissolution profile of Lipanthyl 200M was material to the allowance of the claims in the '881 patent.

98. Philippe Reginault is a named inventor of the '726 patent. He served as Fournier's director of pharmaceutical development in charge of formulation, scale up and analytical development from 1988 to 2002. Beginning in 2002, Reginault served as Fournier's director of pharmaceutical technologies evaluation.

99. Reginault conducted tests and submitted declarations to the PTO during the prosecution of the application that led to the '881 patent. These declarations falsely represented to the PTO that the dissolution rates of prior-art fenofibrate compositions were lower than they actually were, and failed to disclose results showing dissolution rates for such compositions that were higher

than those provided to the PTO. Reginault did not provide test results relating to Lipanthyl 200M, the formulation cited in the Examiner's Statement of Reasons for Allowance, although Reginault had such results in his possession and such results were material.

100. REDACTED

101. REDACTED

102. Reginault did not disclose dissolution data for Lipanthyl 200M that were much better than those submitted to the PTO in the patent application that led to the '881 patent.

103. Reginault did not disclose dissolution data obtained by Fournier for TriCor micronized capsules in 0.025M sodium lauryl sulfate that was much better than that submitted to the PTO.

104. In addition to better dissolution test results, Reginault failed to disclose that the dissolution results for the capsule embodiments of the prior art provided to the PTO may have been lower than the actual dissolution of the active ingredient because of hardening of the capsule gelatin during storage.

105. The information not disclosed by Reginault was highly material to the patentability of the claimed invention.

106. Reginault was aware of the duty to disclose material information when providing submissions to the PTO during the prosecution of a patent application and acknowledged that duty.

107. The information withheld by Reginault was withheld with an intent to deceive the Patent Examiner.

108. In listing and enforcing the '881 patent, Defendants sought to enforce a patent that they knew to be unenforceable. Since the facts evidencing their inequitable conduct were certain to come out during the litigation, Defendants' effort to enforce the patent against any prospective generic competitor was doomed to fail. In fact, no reasonable litigant could have realistically expected to prevail in such a case.

109. Defendants brought the '881 patent litigation pursuant to their policy of filing patent infringement actions without regard to their merit and solely for the purpose of delaying generic entry.

E. ***The Second Exclusionary Conversion***

110. Defendants' abandonment of the Delaware Patent Litigation reveals their true motive for commencing those actions in the first place—to provide Defendants once again with the time needed to modify their TriCor product in order to defeat generic substitutability. While the Delaware Patent Litigation was pending, Defendants were planning yet another product switch, which they implemented in late 2004, while the stay resulting from the Delaware Patent Litigation was still in place.

111. On November 5, 2004, Defendants obtained approval for a new NDA for a different formulation of TriCor, this time in tablets of 48 and 145 mg strengths ("TriCor C"). TriCor

C contains the same active ingredient as TriCor A and TriCor B. By virtue of the modified strength, however, a prescription written for TriCor C cannot be filled with generic TriCor A or generic TriCor B.

112. In addition to modifying the strengths, Defendants also included in TriCor C a technology that allows patients to take TriCor other than with meals. Defendants did not develop this technology themselves, but licensed it from Elan Corporation, plc. Upon information and belief, Defendants entered into an exclusive license with Elan for use of the patent technology with fenofibrate worldwide, and have prohibited Elan from researching and/or developing any oral formulation of fenofibrate using its nanotechnology. Defendants included the licensed technology in TriCor C for the purpose of defeating generic substitutability.

113. Abbott and Fournier then began marketing TriCor C and stopped selling TriCor B, just as they had done in connection with the switch from TriCor A to TriCor B. Defendants directed Abbott's detailers to market only TriCor C to physicians and to urge physicians to stop writing prescriptions for TriCor B; Defendants drained the distribution channel of TriCor B so that pharmacists presented with a TriCor B prescription would call the physician to request a switch to TriCor C; and Defendants caused First Data Bank to list the TriCor B product as obsolete in the NDDF, causing third-party plans to no longer cover branded TriCor B or to charge their customers higher co-pays for Teva's or Impax's TriCor B product.

114. Defendants developed at least one additional twist in connection with the TriCor C exclusionary scheme. Apparently unsatisfied with their prior efforts to drain the distribution channel of TriCor A, Defendants intensified that effort in connection with draining the

channel of TriCor B. This intensification involved a modification of Abbott's policy regarding returned goods.

115. Under Abbott's standard returned-goods policy, wholesalers and retailers do not receive a refund based on the amount of unsold product actually returned to Abbott. Instead, Abbott simply provides a 1% returned-goods allowance at the time of purchase. As part of their scheme to drain all TriCor B from the distribution channel, however, Defendants changed this returned-goods policy as it applied to TriCor B. In or about March 2005, Defendants announced that wholesalers and retailers could return all unsold TriCor B, regardless of quantity, and receive a refund in the amount of the purchase price (less a prompt payment discount and the 1% allowance). This change in policy gave wholesalers and retailers a significant incentive to return all TriCor B and eliminate it from their inventories. This exclusionary tactic had the purpose and effect of ensuring that the distribution channel would be drained of TriCor B before generic versions of TriCor B could enter the market. Defendants' channel-draining strategy would not have made economic sense absent the intended harm to generic competition.

Effects of Defendants' Unlawful Conduct

116. Defendants' exclusionary conduct has delayed or prevented the sale of generic fenofibrate in the United States, and has unlawfully enabled Defendants to sell TriCor at artificially inflated prices. But for Defendants' illegal conduct, generic competitors would have been able to successfully market generic versions of TriCor capsules by the first half of 2002, and additional generic competitors would have entered the market thereafter. TriCor B was introduced solely as part of Defendants' exclusionary scheme and, but for that scheme, would not have been introduced. Moreover, even if TriCor B had been introduced, generic competitors would have begun marketing

generic versions of TriCor B by at least March 5, 2004, and additional generic competitors would have entered the market thereafter. Under no circumstances would Defendants have developed or marketed TriCor C.

117. Defendants' pattern and practice of reflexively filing Hatch-Waxman patent cases and using the resulting 30-month stays to convert the market to a new formulation that is not subject to generic competition, while simultaneously discontinuing the old formulation, is exclusionary and unreasonably restrains competition on the merits. Defendants' conduct has allowed and continues to allow them to maintain a monopoly and exclude competition in the relevant market, to the detriment of all fenofibrate purchasers.

118. If manufacturers of generic fenofibrate had been able to enter the market and compete effectively with Defendants, Plaintiffs (or their assignors) would have substituted lower-priced generic TriCor for higher-priced brand-name TriCor for the vast majority of their fenofibrate purchases and/or would have received lower prices on their purchases of branded TriCor.

119. As a result of Defendants' unlawful and exclusionary conduct, Plaintiffs (or their assignors) were forced to continue to purchase branded fenofibrate from Defendants at monopoly prices rather than generic fenofibrate from a generic manufacturer at much lower prices. Plaintiffs continue to be overcharged by paying higher prices for fenofibrate than would have prevailed in the absence of Defendants' unlawful conduct.

Relevant Product and Geographic Markets

120. The relevant product market is the sale of fenofibrate—i.e., TriCor (in its various formulations) and its AB-rated generic equivalents. The relevant geographic market is the United States. A firm that was the only seller of prescription drugs containing fenofibrate in the

United States could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by Defendants' ability to charge supracompetitive prices for fenofibrate during the period in which Defendants have lacked generic competition.

121. During the relevant period, Defendants' share of the relevant market has been 100% or nearly 100%.

122. Defendants' unlawful actions were taken for the purpose of maintaining Defendants' dominant share of the relevant market and allowing them to continue to charge monopoly prices for fenofibrate free of generic competition.

Count One
Monopolization (15 U.S.C. § 2)

123. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 122 above.

124. At all relevant times, Defendants possessed monopoly power in the relevant market.

125. During the relevant period, Defendants willfully and unlawfully maintained their monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Defendants engaged in an exclusionary scheme that included each of the following (at various times):

a. modifying TriCor A to TriCor B;

b. directing Abbott's detailers to market only TriCor B and to urge physicians not to write prescriptions for TriCor A;

c. withdrawing TriCor A from the market and draining the distribution channel of TriCor A;

d. causing First Data Bank to list TriCor A as obsolete in the NDDF;

e. modifying TriCor B to TriCor C;

f. directing Abbott's detailers to market only TriCor C and to urge physicians not to write prescriptions for TriCor B;

g. withdrawing TriCor B from the market and draining the distribution channel of TriCor B;

h. causing First Data Bank to list TriCor B as obsolete in the NDDF;

i. engaging in sham litigation; and

j. entering into an exclusive license with Elan Corporation.

126. Defendants undertook all of this conduct with the purpose and effect of delaying and/or inhibiting generic competition. Defendants' actions, individually and collectively, were intended to and did suppress rather than promote competition on the merits.

127. Plaintiffs (or their assignors) have been injured in their business and property by reason of Defendants' unlawful monopolization. Plaintiffs' injury consists of paying higher prices for fenofibrate than would have been paid in the absence of Defendants' illegal conduct. Plaintiffs' injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

128. Defendants' violations threaten continuing loss and injury to Plaintiffs unless enjoined by this Court.

Count Two
Conspiracy in Restraint of Trade (15 U.S.C. § 1)

129. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 122 above.

130. At all relevant times, Defendants Abbott and Fournier have been engaged in a contract, combination or conspiracy in unreasonable restraint of trade, the purpose and effect of which have been to delay, impede and restrain competition in the relevant market.

131. At all relevant times, Defendants have possessed market power in the relevant market.

132. During the relevant period, Defendants willfully and unlawfully maintained their market power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Defendants engaged in an exclusionary scheme that included each of the following (at various times):

a. modifying TriCor A to TriCor B;

b. directing Abbott's detailers to market only TriCor B and to urge physicians not to write prescriptions for TriCor A;

c. withdrawing TriCor A from the market and draining the distribution channel of TriCor A;

d. causing First Data Bank to list TriCor A as obsolete in the NDDF;

e. modifying TriCor B to TriCor C;

f. directing Abbott's detailers to market only TriCor C and to urge physicians not to write prescriptions for TriCor B;

g. withdrawing TriCor B from the market and draining the distribution channel of TriCor B;

h. causing First Data Bank to list TriCor B as obsolete in the NDDF;

i. engaging in sham litigation; and

j. entering into an exclusive license with Elan Corporation.

133. Defendants undertook all of this conduct with the purpose and effect of delaying and/or inhibiting generic competition. Defendants' actions, individually and collectively, were intended to and did suppress rather than promote competition on the merits.

134. Defendants' collective conduct has had a substantially adverse effect on competition in the relevant market.

135. Plaintiffs (or their assignors) have been injured in their business and property by reason of Defendants' unlawful conspiracy in restraint of trade. Plaintiffs' injury consists of paying higher prices for fenofibrate than would have been paid in the absence of Defendants' illegal conduct. Plaintiffs' injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

136. Defendants' violations threaten continuing loss and injury to Plaintiffs unless enjoined by this Court

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A judgment for three times the damages actually sustained by Plaintiffs, as determined by a jury;

B. A declaration that Defendants have violated the antitrust laws in the ways described above;

C. Permanent injunctive relief which enjoins Defendants from continuing their illegal conduct, and requires them to take affirmative steps to dissipate the effects of their prior violations;

D. The costs of this suit, including a reasonable attorneys' fee; and

E. Such other and further relief as the Court deems just and proper.

Jury Demand

Plaintiffs demand a trial by jury of all issues so triable.

Respectfully submitted,

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Certificate of Service

I hereby certify that a true and correct copy of the foregoing was served this 23rd day of September 2005 upon all counsel listed on the attached service list.

Scott E. Perwin

230772.1

CERTIFICATE OF SERVICE

I, Elizabeth M. McGeever, hereby certify that on this 23rd day of September, 2005, my co-counsel, Scott E. Perwin, Esquire, caused a copy of the foregoing AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL to be served upon all counsel on the attached service list.

Elizabeth M. McGeever (#2057)

SERVICE LIST

In re Tricor Direct Purchaser Antitrust Litigation
Case No 05-340 (KAJ), District of Delaware

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